

ASSEMBLY BILL

No. 522

Introduced by Assembly Member Plescia

February 16, 2005

An act to amend Section 1261.6 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 522, as introduced, Plescia. Automated drug delivery system.

Existing law provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. Existing law regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system.

This bill would clarify existing law to define pharmacy services and to require a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions. This bill would further clarify existing law to prevent licensed personnel from accessing a different drug or dose of a drug than that approved by a pharmacist.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1261.6 of the Health and Safety Code is
- 2 amended to read:
- 3 1261.6. (a) (1) For purposes of this section and Section
- 4 1261.5, an "automated drug delivery system" means a
- 5 mechanical system that performs operations or activities, other

1 than compounding or administration, relative to the storage,
2 dispensing, or distribution of drugs. An automated drug delivery
3 system shall collect, control, and maintain all transaction
4 information to accurately track the movement of drugs into and
5 out of the system for security, accuracy, and accountability.

6 (2) For purposes of this section, “facility” means a health
7 facility licensed pursuant to subdivision (c), (d), or both, of
8 Section 1250 that has an automated drug delivery system
9 provided by a pharmacy.

10 (3) *For purposes of this section, “pharmacy services” means*
11 *the provision of both routine and emergency drugs and*
12 *biologicals to meet the needs of the patient.*

13 (b) Transaction information shall be made readily available in
14 a written format for review and inspection by individuals
15 authorized by law. These records shall be maintained in the
16 facility for a minimum of three years.

17 (c) Individualized and specific access to automated drug
18 delivery systems shall be limited to facility and contract
19 personnel authorized by law to administer drugs.

20 (d) (1) The facility and the pharmacy shall develop and
21 implement written policies and procedures to ensure safety,
22 accuracy, accountability, security, patient confidentiality, and
23 maintenance of the quality, potency, and purity of stored drugs.
24 Policies and procedures shall define access to the automated drug
25 delivery system and limits to access to equipment and drugs.

26 (2) All policies and procedures shall be maintained at the
27 pharmacy operating the automated drug delivery system and the
28 location where the automated drug delivery system is being used.

29 (e) When used as an emergency pharmaceutical supplies
30 container, drugs removed from the automated drug delivery
31 system shall be limited to the following:

32 (1) A new drug order given by a prescriber for a patient of the
33 facility for administration prior to the next scheduled delivery
34 from the pharmacy, or 72 hours, whichever is less. The drugs
35 shall be retrieved only upon authorization by a pharmacist and
36 after the pharmacist has reviewed the prescriber’s order and the
37 patient’s profile for potential contraindications and adverse drug
38 reactions.

1 (2) Drugs that a prescriber has ordered for a patient on an
2 as-needed basis, if the utilization and retrieval of those drugs are
3 subject to ongoing review by a pharmacist.

4 (3) Drugs designed by the patient care policy committee or
5 pharmaceutical service committee of the facility as emergency
6 drugs or acute onset drugs. These drugs may be retrieved from an
7 automated drug delivery system pursuant to the order of a
8 prescriber for emergency or immediate administration to a
9 patient of the facility. Within 48 hours after retrieval under this
10 paragraph, the case shall be reviewed by a pharmacist.

11 (f) When used to provide pharmacy services pursuant to
12 Section 4119.1 of the Business and Professions Code, the
13 automated drug delivery system shall be subject to all of the
14 following requirements:

15 (1) Drugs removed from the automated drug delivery system
16 for administration to a patient shall be in properly labeled units of
17 administration containers or packages.

18 (2) A pharmacist shall review and approve all orders prior to a
19 drug being removed from the automated drug delivery system for
20 administration to a patient. *The pharmacist shall review the*
21 *prescriber's order and the patient's profile for potential*
22 *contraindications and adverse drug reactions.*

23 (3) The pharmacy providing services to the facility pursuant to
24 Section 4119.1 of the Business and Professions Code shall
25 control access to the drugs stored in the automated drug delivery
26 system.

27 (4) Access to the automated drug delivery system shall be
28 controlled and tracked using an identification or password system
29 or biosensor.

30 (5) The automated drug delivery system shall make a complete
31 and accurate record of all *transactions which will include all*
32 *users accessing the system and all drugs added to or removed*
33 *from the system.*

34 ~~(6) When a pharmacist releases drugs for removal from the~~
35 ~~automated drug delivery system pursuant to paragraph (2), the~~
36 ~~automated drug delivery system shall not provide facility staff~~
37 ~~with access to drugs different from those released. After the~~
38 ~~pharmacist reviews and approves the prescriber's order, access~~
39 ~~by licensed personnel to the automated drug delivery system~~
40 ~~shall be limited only to the prescribed drug authorized by the~~

1 *pharmacist and specific to the patient. When the prescriber's*
2 *order requires a dosage variation of the same drug, licensed*
3 *personnel shall only have access to the drug ordered for that*
4 *scheduled time of administration.*

5 (g) The stocking of an automated drug delivery system shall
6 be performed by a pharmacist. If the automated drug delivery
7 system utilizes removable pockets or drawers, or similar
8 technology, the stocking system may be done outside of the
9 facility and be delivered to the facility if all of the following
10 conditions are met:

11 (1) The task of placing drugs into the removable pockets or
12 drawers is performed by a pharmacist or by an intern pharmacist
13 or a pharmacy technician working under the direct supervision of
14 a pharmacist.

15 (2) The removable pockets or drawers are transported between
16 the pharmacy and the facility in a secure tamper-evident
17 container.

18 (3) The facility, in conjunction with the pharmacy, has
19 developed policies and procedures to ensure that the pockets or
20 drawers are properly placed into the automated drug delivery
21 system.

22 (h) Review of the drugs contained within, and the operation
23 and maintenance of, the automated drug delivery system shall be
24 done in accordance with law and shall be the responsibility of the
25 pharmacy. The review shall be conducted on a monthly basis by
26 a pharmacist and shall include a physical inspection of the drugs
27 in the automated drug delivery system, an inspection of the
28 automated drug delivery system machine for cleanliness, and a
29 review of all transaction records in order to verify the security
30 and accountability of the system.

31 (i) Drugs dispensed from an automated drug delivery system
32 that meets the requirements of this section shall not be subject to
33 the labeling requirements of Section 4076 of the Business and
34 Professions Code or Section 111480 of this code if the drugs to
35 be placed into the automated drug delivery system are in unit
36 dose packaging or unit of use and if the information required by
37 Section 4076 of the Business and Professions Code and Section
38 111480 of this code is readily available at the time of drug
39 administration.

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